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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/054,660 04/03/98 EGGERS

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QM12/0301

PEFFLEY, M

ART UNIT	PAPER NUMBER
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14

3739

DATE MAILED:

03/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/054,660	EGGERS ET AL.
	Examiner	Art Unit
	Michael Peffley	3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- 1) Responsive to communication(s) filed on 19 January 2000.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 41-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 41-61 and 63-87 is/are rejected.
- 7) Claim(s) 62 is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:
1. received.
2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

- 14)  Notice of References Cited (PTO-892)                    17)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 15)  Notice of Draftsperson's Patent Drawing Review (PTO-948)                    18)  Notice of Informal Patent Application (PTO-152)
- 16)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2\_13.                    19)  Other: \_\_\_\_\_

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Applicant's comments and amendments, received January 19, 2000, have been carefully considered by the examiner. In particular, the cancellation of claims 88-119 is acknowledged. Also, applicant's amendments are deemed to overcome the 35 USC 112, second paragraph rejections, and the terminal disclaimer filed with the response has obviated the double patenting issues. The following is a complete response to the January 19, 2000 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 67-87 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's specification fails to adequately describe the means by which application of energy to heart tissue during revascularization would induce the generation of new blood vessels. Moreover, assuming the use of RF energy in performing revascularization procedures would induce the generation of new blood vessels, it seems inherent that all such prior art devices would also yield similar results.

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***Claim Rejections - 35 USC § 102***

Claims 41-46, 51-55, 59, 60, 66-72, 76-81 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Bales et al ('596).

Bales et al disclose an RF catheter device whereby an electrode is used to revascularize and "core" heart tissue (see column 12, lines 29-32). The device includes a catheter with a single or plurality of electrodes thereon, and means to provide an irrigation solution and means to remove tissue and fluid (i.e. aspiration). The device may be used in a monopolar mode with a patient plate return electrode (column 4, line 67 through column 5, line 2), or may be used in a bipolar mode with a return electrode located on the catheter proximal to the active electrode (see column 7). The method of using the device to revascularize or otherwise "core" tissue by providing high frequency current between the active and return electrodes is inherent to the structure and disclosure of Bales et al.

***Claim Rejections - 35 USC § 103***

Claims 47-50 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bales et al ('596) in view of the teachings of Aita et al ('096) and Aita et al ('152).

The Bales et al has been addressed previously. While Bales et al disclose that the catheter device may be used for revascularizing and coring cardiac tissue, there is no specific disclosure as to where the procedure is initiated (i.e. from within the heart or from the external surface of the art).

Aita et al disclose a catheter device for performing TMR procedures. The Aita et al devices utilize an alternative energy source (i.e. laser energy), but otherwise teach

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that it is generally known to perform revascularization procedure which are initiated either from within the heart (Aita et al '096) or on the external surface of the heart (Aita et al '152).

To have provided the Bales et al catheter device either within the heart or on the surface of the heart to perform the revascularization procedure would have been an obvious consideration for one of ordinary skill in the art, particularly since Aita et al teaches that such procedures may be performed from either location.

Claims 56-58, 61, 65 and 82-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bales et al ('596).

While Bales et al disclose the use of the catheter device for performing revascularization procedures and the provision of an irrigant to tissue, Bales et al fail to teach the specific size of the channels or the specific fluid used for irrigation.

The examiner maintains that the size of the channels is based on the size of the catheter device, and that the selected size of the catheter device would be an obvious selection for one of ordinary skill in the art. Further, the examiner takes official notice that catheter devices which employ a source of irrigation generally, or very often, use saline as the irrigant.

To have provided the Bales et al device in any reasonable size would have been an obvious design consideration for one of ordinary skill in the art. Further, to have used saline as the irrigation fluid in the Bales et al device would have been an obvious selection for one of ordinary skill in the art since saline is a very commonly used irrigant in such catheters.

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Claims 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bales et al ('596) in view of the teaching of Mueller et al ('164).

Again, Bales et al teaches of the use of the RF electrode catheter for performing revascularization procedures. However, Bales et al do not specifically teach of providing curved or substantially "U-shaped" channels in heart tissue.

Mueller et al disclose a similar catheter device which uses an alternative energy source (i.e. laser) to revascularize heart tissue. More specifically, Mueller et al teach of using the device to create non-linear and substantially U-shaped channels in heart tissue (see figures).

To have modified the Bales et al catheter to create curved channels in heart tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Mueller et al.

***Allowable Subject Matter***

Claim 62 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed January 19, 2000 have been fully considered but they are not persuasive.

Applicants have argued that the phrase "smooth muscle coring" is unclear in the Bales et al reference, and that the phrase is sufficiently ambiguous that it does not teach one of ordinary skill in the art the claims as set forth in the instant application.

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The examiner disagrees, and maintains that the description of smooth muscle coring is not only clear, but that the Bales et al reference clearly anticipates the claim language. The Bales et al reference makes repeated references to "coring" through tissue to create a channel therein. For instance, column 12, lines 3-8 of Bales et al disclose how the device is used for "coring" through tissue. The device is advanced through plaque deposits within blood vessels. The "cored" plaque is then removed through a suction port. More specifically, the recitation in column 12, lines 22-40 are deemed to clearly describe that smooth muscle cardiac tissue is "cored" for revascularization. The term "coring" is not unclear (i.e. to core, or penetrate, through tissue to create a channel), particularly since the entire Bales et al patent is directed to coring, or creating channels, through occluded vessels. Also, the term "revascularization" is generally known in the art, particularly in the cardiac treatment art. As such, the phrase "smooth muscle coring in cardiac revascularization" (column 12, lines 31-32) is deemed to adequately describe the creation of a channel in heart tissue.

With respect to applicant's assertion that Bales et al fail to teach the volumetric removal of tissue, the examiner maintains that Bales et al teach the removal of ablated, or "cored", tissue. Specifically, Bales et al provide a suction means to remove tissue. Disclosure of this may be found in the Abstract, Summary of the Invention, and throughout the body of the patent.

With respect to the limitation of "inducing the generation of new blood vessels in the region of the target site", the examiner maintains that the Bales et al device would

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inherently perform this same function since it is used in identical procedures and operates in the same manner (i.e. through the use of RF energy to core tissue). Further, applicant's specification fails to adequately describe this limitation, as addressed previously, or why applicant's procedure would provide an unexpected advantage for inducing generation of blood vessels over other prior art devices.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on 9 hour.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda M Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley/mp  
Primary Examiner  
Art Unit 3739  
February 28, 2000

*Michael Peffley*  
MICHAEL PEFFLEY  
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